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PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE
SUITE 1200
ATLANTA GA 30361

In re Application of	:
Stauss et al.	:
Serial No.: 10/003,983	: PETITION DECISION
Filed: October 31, 2001	:
Attorney Docket No.: ICI 103	:

This is in response to the petition under 37 CFR § 1.181 and 37 CFR § 1.144, filed October 17, 2005, requesting withdrawal of an improper restriction requirement

BACKGROUND

A review of the file history shows that the application was filed October 31, 2001 under 35 U.S.C. 111(a). The application as filed contained 41 claims. On October 4, 2004 the examiner mailed a restriction requirement dividing the claims into 14 groups. On February 2, 2005 applicants filed a response in which they elected Group I, with a further species election of SEQ ID No: 1 containing peptide bonds. Applicants traversed the restriction requirement, arguing that the claims should have been restricted to no more than 6 groups. On May 23, 2005 the examiner mailed a first Office action on the merits, in which the restriction requirement was made final. However, the requirement for election of species was withdrawn in part. The examiner searched each of SEQ ID Nos: 1-16, including only peptide bonds.

DISCUSSION

Applicants now argue that the claims should be restricted to no more than 4 groups.

First Applicants argue that groups I, II, XIII, drawn to peptides, nucleic acids and a library of peptides, should be examined together. Applicants reason that the peptides and the peptide library are not independent because the peptides are essential to both groups. This argument is not persuasive because the groups are not drawn to the same peptides. Claim 40 (group XIII) is drawn to a library of "peptides of human CD45 polypeptide" and thus is limited to human CD45 and fragments thereof. Claim 1 (group I) includes peptides *comprising* portions of human CD45 (no lower limit to the fragment size) and variants of said portions (no minimum degree of similarity to

native sequence specified). Thus group I clearly includes many peptides which would not be found in the library of group XIII, necessitating different searches. Group XIII also specifies that certain information be recorded for each member of the library, requiring additional search beyond the search for the peptide structures themselves. With regard to the nucleic acids of group II, Applicants cite *Wallach* for the proposition that if an amino acid sequence is known, it is routine to obtain the nucleotide sequence encoding it. This argument is not persuasive because, as pointed out above, claim 1 does not define the complete structure of the claimed peptides. "Given the amino acid sequence, one can determine the chemical structure of all nucleic acid molecules that can serve the function of encoding that sequence. Without that sequence, however, or with only a partial sequence, those structures cannot be determined..." (*Wallach*, p. 1943). Since the peptides of claim 1 are not defined by specific structures, the search required for the nucleic acids of claim 8 (group II) would be burdensome, not straightforward.

Applicants argue that groups III-VII, XII and XIV are connected in operation by the antigen presenting cells and the peptides of group I. This argument is not persuasive. The library of group XII recognizes "CD45 peptides" (not limited to human CD45) and the library of group XIV is loaded with "peptides of human CD45." The products of groups III and VII contain peptides as defined in claim 1 which, as discussed above, include fragments and variants of human CD45, potentially fused with other peptides. The kit of group III would not render the cytotoxic T lymphocytes of group VII obvious and, absent any admission by Applicants to that effect, restriction between these two groups is considered proper. Therefore the various products are patentably distinct. The methods of groups IV-VI can be viewed as either methods of using the product of group III or methods of making the product of group VII. Had either product been elected and found allowable, method claims of equivalent scope could have been rejoined, as stated by the examiner in the restriction requirement.

Applicants propose that groups VIII and IX should be a single group. No reasons are given. It is noted that the proteins of group VIII are claimed in terms of function, not structure, and also include structurally undefined "functional equivalents." As discussed above for groups I and II, the lack of complete structural information for the peptides of group VIII would make it difficult, if not impossible, to search for the nucleotide sequences encoding said peptides. Since the peptides as claimed would not render the nucleic acids obvious, and because it would be a burden to search both inventions, restriction is proper.

Applicants argue that groups X and XI should be combined into a single group because they are connected in operation (treatment with CTLs) and effect (treatment of malignant cells). This argument is not persuasive. First, the CTLs are not defined identically in the two groups of claims so it is not clear whether it is, in fact, the same product administered in the two methods. Second, one invention is a method of killing "target cells," which need not be malignant. Finally, the process steps recited in each method are different, necessitating different searches.

Applicants further argue that it would be "effortless" to search all of the claimed inventions together. This is not found persuasive for the reasons discussed above.

Applicants argue that claim 19 has been placed into 3 groups. It is agreed that claim 19 should have been treated as a linking claim. Since none of the 3 groups including claim 19 were elected, this is a moot point. However, the examiner should make note of this and utilize linking claim practice should the same claims be presented in a continuation or divisional application.

Applicants argue that the election of species requirement is improper. It is not clear to which requirement Applicants refer. Assuming it is the requirement for election of a single peptide within elected group I, the argument is mostly moot since all 16 named species were searched by the examiner. The only remaining division within group I is between peptides which contain non-peptide bonds and those which do not. Applicants hint that these two sub-genera should be considered unpatentable over each other, but stop short of stating such on the record. Absent any evidence or unambiguous statement that one type of peptide would render the other obvious, the election of species is deemed proper. Applicants are reminded that, should the elected subgenus (no non-peptide bonds) be found allowable, the non-elected subgenus will also be considered.

DECISION

Applicants' petition is **DENIED**.

Any request for reconsideration of this decision must be made by way of a renewed petition and must be filed within **TWO MONTHS** of the date of mailing of this decision in order to be considered timely.

Should there be any questions about this decision please contact Marianne C. Seidel by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 703-872-9306.

George Elliott
Director, Technology Center 1600